Questions for follow-up from the Medicare Part D Videoconference on May 18, 2005

1. Can a local Department of Social Services share LIS enrollee/applicant information with the local SHIP/VICAP, especially given HIPAA requirements?

   CMS Response: Awaiting a response.

2. What are “biologicals” and please provide some examples?

   CMS Response: Technically, "biologicals" are substances described in Section 1927(k)(2)(B) of the Act. Biologicals are drugs that are produced in living systems as opposed to drugs that are chemical compounds. They are either directly extracted from animal/human tissue or blood or are manufactured in living organisms that act as biological factories. Some examples you are probably familiar with are insulin, growth hormone and vaccines.

3. Given certain exclusions and restrictions on the PDPs, will plans be able to adequately treat HIV/AIDS patients with severe wasting syndrome?

   CMS Response: CMS, in conducting the formulary review, is paying particular attention to drugs covered for HIV/AIDS patients. Drugs such as Magesterol will be on the formulary for AIDS wasting. Medicare Part B covers parenteral nutrition for individuals with a non-functioning digestive tract. For all other medically accepted indications, coverage would be under Part D.

4. In 2006, the dual eligibles retain their LIS status for the entire year even if they lose Medicaid eligibility during the year. Will the same apply for 2007?

   CMS Response: Yes, CMS will maintain the deemed files and will not make deletions during the year except for the deceased and persons who were erroneously reported as Medicaid/MSP/SSI-eligible. (Those who were erroneously reported will be terminated from the subsidy prospectively based on the month in which CMS learns of the error.) Each year, in early autumn, CMS will compare current data from the states and SSA to the previous year's data on the deemed. Those who no longer appear as dually eligible will not be deemed for the next calendar year but will retain subsidy eligibility through December 31 of the year of the redetermination. These individuals regain deemed status if their state or SSA later reports that they regained dual eligibility. Their alternative is to apply for the subsidy for the next calendar year.

5. Who will be monitoring the PDP telemarketing for fraud? May they also go door-to-door with their list of eligibles and how will this be monitored for fraudulent or misleading activities?

   CMS Response: Draft marketing guidelines are available at **http://www.cms.hhs.gov/pdps/PartDMrktngGdlnsCut1-FnlCMS5-9-05ANB.pdf**

   These guidelines provide that Part D Plans must comply with the National-Do-Not-Call Registry; honor "do not call again" requests; abide by Federal and State calling hours. In addition, because of the complex nature of Part D offerings, enrollment by outbound telemarketers is not allowed. Rather, outbound telemarketing may be used solely to solicit requests for pre-enrollment information, describe benefits, and to alert existing beneficiaries to new benefits or health related offers. Part D Plans can also conduct follow-up calls to establish receipt of requested information and to field questions regarding programs.

   All Part D Plan telemarketing scripts must be reviewed and approved by CMS prior to use within the marketplace. Scripts must include a privacy statement clarifying that the beneficiary is not required to provide any information to the Plan representative and that the information provided will in no way affect the beneficiary's membership in the Plan. Part D Plans are prohibited from requesting beneficiary identification numbers, (e.g., Social Security Numbers, bank account numbers, credit card numbers, HICN, etc.). Plans are allowed to say they are contracted with Medicare to provide Prescription Drug Benefits or that they are Medicare Approved MA-PD/PDP. Plans cannot use language in outbound scripts that imply that they are endorsed by Medicare, calling on behalf of Medicare, calling for Medicare.

   There are numerous means to report suspected fraud or abuse: contact 1-800-Medicare, 1-800-HHS-TIPS, regional office plan managers, local VICAP and Department of Aging staff.

6. What methods will be available for pharmacy providers to verify Part D coverage? Is it just 1-800-MEDICARE?

   CMS Response: The 1-800-Medicare is not available for pharmacy providers. Contracted pharmacies will have to call the plans directly. We may have a means for beneficiaries to use the IVR system to allow beneficiaries to enter their Medicare number and other identifying information and find out their enrollment status.

7. Is there a comprehensive glossary of terms for Medicare Part D rules and regulations?

   CMS Response: See Enclosure from the regulation. 42 CFR § 423.4 has a list of definitions of terms in the regulation. Some of the subparts utilize specific definitions as well. There is also a list of acronyms in the preamble, which we are including in the enclosure.

8. Will SSA give individual Medicare beneficiary names and addresses to the PDPs to help market their plans? What are the PDP marketing guidelines?

   CMS Response: See above link to marketing guidelines. CMS will not be providing beneficiary names and addresses to PDPs.

9. If a QMB doesn't do anything about enrollment into a PDP, CMS will facilitate the individual's enrollment effective June 1, 2006. Since the QMB will not pay a premium, why not enroll them for January 1, 2006?

   CMS Response: The statute authorizes auto enrollment for full dual beneficiaries on 1/1/06, as they were already receiving coverage for their prescription drugs. It does not give the authority to auto enroll QMBs. However, it is our goal to provide information and education so that all Medicare beneficiaries, including QMBs, will be able to select an appropriate PDP on or before 1/1/06.

10. Many Medicare and dual eligibles in Virginia receive services from Community Services Boards and Health Authorities. They receive Mental Health drugs from the State's Aftercare Pharmacy system. Will the cost of these drugs be applied to TROOP?

    CMS Response: Awaiting an answer.

11. Why aren't benzodiazepines included in formularies? They are quite commonly used with this population.

    CMS Response: They are excluded by statute. A recent SMD letter indicated that Medicaid can receive FFP for covering this drug for their dual eligibles.

12. Allowing plans to switch drugs within a category during the plan year could be disastrous, even with a 60-day notice. Why are the plans being allowed to do this?

    CMS Response: CMS will review any formulary changes that are made mid-year and will question any that do not seem appropriate. The changes requested may be a result of manufacturer price increases or new drugs available in the marketplace.

13. Virginia has a unique system, funded by the Department of Mental Health Mental Retardation and Substance Abuse Services, an Aftercare Pharmacy system which uses the Minnesota Multi state buying contact---very good prices, not for profit. Medicare recipients with Mental Health are already well connected to this system. Could plans be encouraged to contract with Aftercare as a preferred provider?

    CMS Response: Individuals interested in contracting with the plans, can submit information to CMS and it will be made available at our website. See http://www.cms.hhs.gov/pdps/Intrstd3rdPrtyInfo.asp or contact Marietta.Mack@cms.hhs.gov

14. Why did CMS decide to allow drug programs to telemarket, when States have had so many problems with telemarketing? Those of us who work in the system with Senior have been teaching them to trust no one on the phone unless they make the call. This really opens us the opportunity for scans and frauds to be perpetrated on seniors over the phone again.

    CMS Response: This is the similar to the rules we allow for Medicare Advantage plans.

15. Will applicants receive a receipt for the scannable applications if they are sent in now? Or, will the receipt be available only for the internet applications that will be available beginning July 1?

    CMS Response: The applicant will receive written confirmation that their application was received.

16. What is counted as income and how does it affect the Food Stamps program?

    CMS Response: CMS has developed a low-income subsidy website with numerous fact sheets that can respond to these questions. The document can be located at the following website: http://www.cms.hhs.gov/medicarereform/lir.asp

17. If a person waits 13 months to join and next year the plan costs $39 per month, will the penalty be 12% of $37 plus 1% of $39?

    CMS Response: If a person is eligible for Medicare and does not sign up during the initial open enrollment period and they do not have creditable coverage from another source, they will be assessed a penalty of 1% a month of the base premium at the time they decide to enroll.

18. Will a list of legitimate Part D plans be published so that consumers and law enforcement officials will be able to sort out frauds?

    CMS Response: Yes.

19. If telemarketing of plans is permitted, will the FTC "Do not call" list shield potential customers of the plans from such calls?

    CMS Response: Yes.

20. If one gets a benzodiazepine and it is paid for by the state of Virginia, does it count toward the $3,600 for those who receive "extra help"?

    CMS Response: No – since this is not a covered Part D drug. If the State decides to continue covering these drugs under Medicaid, they will receive FFP, but the costs will not count toward TrOOP.

21. With respect to the income question on the LISA, do you mean gross income or take-home pay after social security, Medicare, FICA, and 401(k) and other amounts such as cafeteria plan amounts are deducted?

    CMS Response: Gross income is counted.

22. What about income received as a result of refundable tax credits such as the earned income credit and the additional child tax credit – do they count as other income?

    CMS Response: As with tax refunds, these are not considered income and therefore are not counted for "extra help" determinations.

23. If the 1st premium is due Jan. 1, 2006, will it come out of the SS check the recipient gets in Jan.?

    CMS Response: The answer has not yet been determined.

24. Folks on SLMB will receive extra help in group 2. If they meet a spenddown and are enrolled on full Medicaid will they automatically move to Group 1 and have a lower co-pay?

    CMS Response: CMS will share data obtained from the state regarding deemed status. SSA will only move an individual from one category to another when the information is provided to them by CMS.

25. Dually eligible full Medicaid folks have special enrollment periods (SEP) and can switch their Part D drug plans at any time. Do the QMB, SLMB,QI-1 also have SEP or can they only change during the annual election period after their original choice of a drug plan after enrollment?

    CMS Response: Full duals have an ongoing special enrollment period. At this time, QMB, SLMB, and QIs will have one opportunity to switch their plans and after that they will have to wait for the annual open enrollment period.

26. Does the $37.00 for Part D apply towards the deductible of $250.00 and/or will it apply to the $3600.00 out of pocket?

    CMS Response: The premium will not apply toward the deductible or out of pocket expenses.

27. How is the annual redetermination of eligibility for "extra help" done? Will non-deemed enrollees get a new application to fill out?

    CMS Response: In 2006 near the end of the year, every non-deemed extra help beneficiary will receive a new SSA 1020 as a redetermination of his\her eligibility. This will be a "passive" redetermination-meaning the beneficiary only has to return the redetermination form "if" there has been a change.

28. Please define who is a dependent relative who depends upon the Medicare recipient for at least 50% of his/her support. For example, a 46 year old son who lives with his mother who is a Medicare Part D recipient and the mother supports him.

    CMS Response: Any individual related by blood, marriage or adoption who lives with and is receiving at least 1/2 support from the Medicare beneficiary or his/her spouse.

29. For Veterans who receive their prescriptions thru the Veterans Administration, will the VA continue to provide their drugs?

    CMS Response: The VA has not made a final decision yet on how they will coordinate with Part D.

30. Will the Part D premium be deducted from the SSA check?
    A. This is an option. The beneficiary must elect the method of payment of the premium when he/she enrolls in a plan. The beneficiary has the option to have the premium deducted from the SSA check or to make a payment directly to the plan.

31. If a person applies for a spouse for Extra Help, do both spouses have to sign the application?

    CMS Response: No.

32. If SSI allows a man and woman to present themselves as man and wife (even thought they are not legally married), can the man or woman file an application for Extra Help on behalf of each other?

    CMS Response: The man or woman may file for extra help on behalf of each other. Anyone who is acknowledged by the beneficiary as his/her "representative" can apply on behalf of an individual for extra help.

33. Are all types of “help” considered in-kind support and counted against an applicant’s eligibility for LIS?

    CMS Response: No, see the SSA 1020 for definition of in-kind support and what is counted as income for extra help.

34. If a Medicare beneficiary has a grandchild living in her home and receives child support, will this be counted as income?

    CMS Response: No, only the income of the individual and his/her living spouse's income will be counted for an extra help determination. This child support is income for the child.

Appendix

Definitions in regulation
42 CFR §423.4 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Actuarial equivalence means a state of equivalent value demonstrated through the use of generally accepted actuarial principles and in accordance with section 1860D–11(c) of the Act and with CMS actuarial guidelines.

Brand name drug means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(c)), including an application referred to in section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 USC 355(b)(2)).

Cost plan means a plan operated by a Health Maintenance Organization (HMO) or Competitive Medical Plan (CMP) in accordance with a cost-reimbursement contract under section 1876(h) of the Act.

Eligible fallback entity or fallback entity is defined at §423.855.

Employer-sponsored group prescription drug plan means prescription drug coverage offered to retirees who are Part D eligible individuals under employment-based retiree health coverage (as defined in §423.882) approved by CMS as a prescription drug plan.

Fallback prescription drug plan is defined at §423.855.

Formulary means the entire list of Part D drugs covered by a Part D plan.

Full-benefit dual eligible individual has the meaning given the term at §423.772, except where otherwise provided.

Generic drug means a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(j)) is approved.

Group health plan is defined at §423.882.

Insurance risk means, for a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitutions, nor does it include elements potentially in the control of the pharmacy (for example, labor costs or productivity).

MA stands for Medicare Advantage, which refers to the program authorized under Part C of title XVIII of the Act.

MA plan has the meaning given the term in §422.2 of this chapter.

MA–PD plan means an MA plan that provides qualified prescription drug coverage.

Medicare prescription drug account means the account created within the Federal Supplementary Medical Insurance Trust Fund for purposes of Medicare Part D.

Monthly beneficiary premium means the amount calculated under §423.286 for Part D plans other than fallback prescription drug plans, and §423.867(a) for fallback prescription drug plans.

PACE Plan means a plan offered by a PACE organization. PACE organization is defined in §460.6 of this chapter.

Part D eligible individual means an individual who meets the requirements at §423.30(a).
Part D plan (or Medicare Part D plan) means a prescription drug plan, an MA-PD plan, a PACE Plan offering qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage.

Part D plan sponsor or Part D sponsor refers to a PDP sponsor, MA organization offering a MA-PD plan, a PACE organization offering a PACE plan including qualified prescription drug coverage, and a cost plan offering qualified prescription drug coverage.

PDP region means a prescription drug plan region as determined by CMS under §423.112.

PDP sponsor means a nongovernmental entity that is certified under this part as meeting the requirements and standards of this part that apply to entities that offer prescription drug plans. This includes fallback entities.

Prescription drug plan or PDP means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in §423.272 and that is
offered by a PDP sponsor that has a contract with CMS that meets the contract requirements under subpart K of this part. This includes fallback prescription drug plans.

Service area (Service area does not include facilities in which individuals are incarcerated.) means for -- (1) A prescription drug plan, an area established in §423.112(a) within which access standards under §423.120(a) are met; (2) An MA-PD plan, an area that meets the definition of MA service area as described in §422.2 of this chapter, and within which access standards under §423.120(a) are met; (3) A fallback prescription drug plan, the service area described in §423.859(b); (4) A PACE plan offering qualified prescription drug
coverage, the service area described in §460.22 of this chapter; and (5) A cost plan offering qualified prescription drug coverage, the service area defined in §417.1 of this chapter.

State Pharmaceutical Assistance Program (SPAP) means a State program that meets the requirements described under §423.464(e)(1).

Subsidy-eligible individual means a full subsidy eligible individual (as defined at §423.772) or other subsidy eligible individual (as defined at §423.772).

Tiered cost-sharing means a process of grouping Part D drugs into different cost sharing levels within a Part D sponsor's formulary.

Acronyms listed in Preamble

ABN Advanced beneficiary notice
ADAP AIDS Drug Assistance Program
AEP Annual coordinated election period
AHRQ Agency for Healthcare Research and Quality
AI/AN American Indians and Alaska Natives
AIC Amount in controversy
ALJ Administrative Law Judge
AMA American Medical Association
AMCP Academy of Managed Care Pharmacy
ANCI American National Standards Institute
AO Accreditation organization
ASAP American Society of Automation in Pharmacy
ASHP American Society of Health Systems Pharmacists
AWP Average wholesale price
BBA Balanced Budget Act
BLS Bureau of Labor Statistics
CAHP Consumer Assessment of Health Plan
CBI Confidential business information
CBO Congressional Budget Office
CCIP Chronic care improvement programs
CCP Comprehensive Compliance Program
CFR Code of Federal Regulations
CHOW Change of ownership
CMP competitive medical plan
CMS Centers for Medicare & Medicaid Services
COB Coordination of benefit
COBRA Consolidated Omnibus Budget Reconciliation Act (of 1985)
CPI-PD Consumer Price Index for Prescription Drugs and Medical Supplies
CPT Current Procedural Terminology
CY Calendar year
DAB Departmental Appeals Board
DHS Designated health services
DME Durable medical equipment
DoD Department of Defense
DOL Department of Labor
DUR Drug utilization review

EOB explanation of benefits
ERISA Employee Retirement Income Security Act of 1974
ESRD End stage renal disease
FAR Federal Acquisition Regulation
FDA Food and Drug Administration
FEHBP Federal Employee Health Benefits Program
FFP Federal financial participation
FOIA Freedom of Information Act
FQHCs Federally qualified health centers
FPL Federal poverty level
FR Federal Register
FSA Flexible savings account
FY Fiscal year
HEDIS Health plan Employer Data and Information Set
HHS Department of Health and Human Services
HIC Health insurance claim
HIPAA Health Insurance Portability and Accountability Act of 1996
HMO Health maintenance organization
HPMS Health Plan Management System
HRA Health reimbursement account
HRSA Health Resources and Services Administration
HSA Health savings account
ICFs/MR Intermediate care facilities for the mentally retarded
IDIQ Indefinite duration, indefinite quantity
IEP Initial enrollment period
IHS Indian Health Service
IRE Independent review entity
I/T/U Indian Tribes and Tribal organizations, and urban Indian organizations
JCHACO Joint Commission on Accreditation of Health Care Organizations
LIS Low-income subsidy
LTC Long term care
MA Medicare Advantage (formerly Medicare+Choice)
MA-PD Medicare Advantage prescription drug plans
MAC Medicare Appeals Council
MAX Medicaid Analytic extract
MCBS Medicare Current Beneficiary Survey
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MSA Medicare savings account
MSIS Medicaid Statistical Information System
MSP Medicare Secondary Payor
MTMP Medication Therapy Management Program

NAIC National Association of Insurance Commissioners
NCQA National Committee for Quality Assurance
NCPDP National Council for Prescription Drug Programs
NCVHS National Center for Vital and Health Statistics
NDC National Drug Code
NHE National Health Expenditure
NPA National PACE Association
NPI National Provider Identifier
OACT Office of the Actuary (CMS)
OBRA Omnibus Budget Reconciliation Act
OCR Office for Civil Rights
OEPI Open enrollment period for institutionalized individuals
OIG Office of the Inspector General
OPM Office of Personnel Management
P&T Pharmaceutical and therapeutic
PBA Pharmacy benefit administrator
PBMs Pharmacy benefit managers
PBP Plan Benefit Package
PDP Private prescription drug plan
PDSC Phased-down State contribution
PFFS Private fee-for-service plan
PHI Protected health information
PhRMA Pharmaceutical Manufacturers and Researchers of America
PPO Preferred provider organization
PPV Pharmaceutical Prime Vendor
PSO Provider-sponsored organization
QDWIs Qualified disabled and working individuals
QIl Qualified individuals
QIO Quality Improvement Organization
QMB Qualified Medicare beneficiaries
REACH Regional Education About Choices in Health
RHC Rural Health Center
SCHIP State Children's Health Insurance Program
SEP Special enrollment period
SHIP State health insurance assistance program
SLMB Special Low-Income Beneficiaries
SOW Scope of work
SPAP State Pharmaceutical Assistance Program
SPD Summary Plan Description
SPOC Single point of contact
SSA Social Security Administration
SSI Supplemental Security Income
SSRI Selective serotonin reuptake inhibitor
SSSGs Similarly Sized Subscriber Groups

TANF Temporary assistance for needy families
TrOOP True out-of-pocket
U&C Usual and customary
URAC Utilization Review Accreditation Commission
USP U.S. Pharmacopoeia
VA Department of Veterans Affairs
VDSA Voluntary data sharing agreement